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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,266	08/27/2001	Gust H. Bardy	032580.0028.CIP1	5571

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EXAMINER	
DROESCH, KRISTEN L	

ART UNIT	PAPER NUMBER
3762	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/940,266	Applicant(s) BARDY ET AL.	
	Examiner Kristen L Droesch	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2/6/04 (response, IDS)*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *121-132* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *130-132* is/are allowed.

6)☒ Claim(s) *121,122,125 and 129* is/are rejected.

7)☒ Claim(s) *123,124 and 126-128* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 121-122, and 129 are rejected under 35 U.S.C. 102(b) as being anticipated by Causey, III (5,411,547).

Regarding claims 121-122, Causey III shows a method of treating an abnormally fast sinus rhythm comprising providing an implantable stimulus device; providing a lead system including implanting the leads to areas that are exclusive of the patient's heart; sensing an event in the patient's sinus rhythm; coupling the power source to the energy storage system (capacitor); storing energy in the energy storage system; and discharging energy from the energy storage system using the lead to a subcutaneous volume of the patient (Col. 1, lines 36-39; Col. 3, lines 28-53).

With respect to claim 129, Causey III shows the step of discharging energy is performed to produce a biphasic waveform (Col. 1, lines 52-58).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 125 is rejected under 35 U.S.C. 103(a) as being unpatentable over Causey, III (5,411,547) in view of Bardy (5,292,338). Causey III is as explained before. Causey fails to specifically point out that the defibrillator is implanted subcutaneously between the third rib and the twelfth rib of the patient, but only mentions that a known defibrillator is used. Attention is directed to Bardy which teaches a known defibrillator that is implanted in the left infraclavicular pectoral region. As seen in Fig. 2 of Sanchez, Zambrano (5,895,414) the clavicle (21) is located approximately at the same location or level as the third rib (23) in the pectoral region. Thus, if the known defibrillator Bardy is implanted in the left infraclavicular pectoral region, it is advanced below the third rib and above the twelfth rib. Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to implant the defibrillator of Causey III subcutaneously between the third rib and the twelfth rib of the patient as is known for implanting known defibrillators.

Allowable Subject Matter

5. Claims 123-124, and 126-128 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. Claims 130-32 are allowed.

Regarding claims 123-124, the prior art of record fails to teach or suggest a method including providing a implantable stimulus device in a patient and providing a lead system for the stimulus device by implanting the leads to areas exclusive of the heart; storing energy in the energy storage system and discharging energy from the energy storage system to a subcutaneous

volume of the patient in combination with repeatedly storing and discharging energy at a an initial rate set to overdrive the abnormally fast rhythm and then at a reduced rate.

With respect to claim 126, the prior art of record fails to teach or suggest a method including providing a implantable stimulus device in a patient and providing a lead system for the stimulus device by implanting the leads to areas exclusive of the heart; storing energy in the energy storage system and discharging energy from the energy storage system to a subcutaneous volume of the patient in combination with implanting the stimulus device at about the left axillary line with the lead system including a lead extending medially therefrom.

Regarding claim 127, the prior art of record fails to teach or suggest a method including providing a implantable stimulus device in a patient and providing a lead system for the stimulus device by implanting the leads to areas exclusive of the heart; storing energy in the energy storage system and discharging energy from the energy storage system to a subcutaneous volume of the patient in combination with implanting the stimulus device at a subcutaneous location along the inframammary crease of the patient.

With respect to claim 128, the prior art of record fails to teach or suggest a method including providing a implantable stimulus device in a patient and providing a lead system for the stimulus device by implanting the leads to areas exclusive of the heart; storing energy in the energy storage system and discharging energy from the energy storage system to a subcutaneous volume of the patient in combination with the lead system including a first electrode and the implantable stimulus device including the second electrode on a housing.

Regarding claim 130-132, the prior art of record fails to teach or suggest a method including providing a implantable stimulus device subcutaneously in a patient at approximately

the left anterior axillary line of the patient between the third and twelfth ribs and providing a lead system for the stimulus device by passing the lead system to locations exclusive of the patient's heart and discharging energy from the energy storage system via first and second electrodes disposed within the patient exclusive of the patient's heart.

Response to Arguments

7. Applicant's arguments with respect to claims 121-122, 125, and 129 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Droesch whose telephone number is 703-605-1185. The examiner can normally be reached on M-F, 10:00 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kristine Dowell

kld

Patricia Bianco
Primary Examiner
3/22/04